MEDICAL IMAGING
CSO Customer Support Operations

Field Service Bulletin No. 8

Order No.: DD+DIS155.01E

1 piece UOP9C MA1

ADC System Components

Type 4406

Rating			When?		
safety relevant	reliability	new function	immediately	next service	as required
X			**X**		

Please file this document in section 13 of your technical documentation

Patient Images associated with incorrect patient demographic information

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Appendix: Customer Letter

Addendum A to the Customer Letter

1 Patient Images associated with incorrect patient demographic information

The information is safety relevant for ADC systems integrated in a PACS system with or without RIS system as a mismatch of image and patient demographics may occur. This may only happen in case of manual modifications of patient demographics in the ADC system or when recalling data from a history list.
This may occur with all released versions of PRID (incl. PRID 1.2.07), VIPS (incl. VIPS1.1.09) and ADC-QS (incl. ADC-QS1.0.05).

Product Issue Circumstance

The patient demographic information can be changed inadvertently by the user causing the image to be associated with the wrong patient and subsequently merged into the wrong patient folder on a Picture Archiving Communication and Storage (PACS) system. The problem may occur in the system configurations and under the conditions described below.

The problem does not occur when images are exclusively printed.

Reason

System Configuration: ADC, RIS and PACS
Conditions: UID transferred from RIS to PRID
The user retrieves examination information from the RIS to the PRID and modifies the data manually. The data maybe changed manually by using the "New Patient" button, "History List", "Patient List", "Recall" button or entering data manually on the PRID or processing station. Consequently, the patient data from the RIS is overwritten, while the **StudyUID remains the same**, or in other words, the StudyUID is linked to different patient demographics on the RIS and on the PRID.

System Configuration: ADC, RIS and PACS (where the study instance UID is not transferred from the RIS to the PRID) or ADC and PACS without RIS:
The user retrieves examination information from the RIS to the PRID, or enters the data manually. The data (including StudyUID created by the PRID) will be related to the cassette / image, and sent via the processing station to the PACS system. When the user sends the study again with modified information to the PACS, this modification can be lost.

System Configuration: ADC workstation only
Conditions: The user corrects patient data via the info dialog
The user inadvertently misidentifies the patient or study (e.g. keeping the previous patient data or typing an error in an ID or name) and attempts to correct the information via the info dialog on the workstation. The user may unknowingly modify other patient images or studies.

Solution At the moment there is no technical solution to prevent this problem. The next software releases of PRID, VIPS and ADC-QS will fix that problem. Those next software releases are currently under test.

Measures

- The attached customer letter was sent to all customers by the ADC senior marketing manager.
- It is a **must** to inform the customer how he can avoid the problem:
  - Study data retrieved from the RIS must not be changed on the ADC system.
  - Necessary modifications must be done on the PACS.
- It is a **must** to modify all systems in the field as soon as the recommended versions of PRID, VIPS and ADC-QS are available

July 3, 2001

Account Name
Radiology Department
Address

Attn: (Customer Name)

We at Agfa Corporation want to thank you for your purchase of an ADC Computed Radiography system. We appreciate your confidence in both our company and the products and services that we produce.

At Agfa, we continuously monitor ourselves, our products and our processes to ensure that our customers receive the highest quality product and services. Our quality monitoring system determined that a significant issue may occur with the currently released versions of ADC and PACS which can affect the demographic information utilized by other ADC software including ADC ID/Preview, ADC VIPS (Sun Based Processing Server) and ADC QS (Window NT based Processing Server). Under certain infrequent circumstances, patient images may be associated with incorrect patient demographic information when retrieving patient information first from a Radiographic Information System (RIS) using Rislink software or entering the data manually at the ADC workstation or PRID.

Addendum A describes the circumstances that causes this problem.

Agfa is developing a software change to resolve this issue. This software remedy is currently being thoroughly tested prior to deployment throughout the customer base. We expect, at this time, a targeted date for release of this software upgrade to be mid to end August 2001. We will notify you immediately when a solution is available.

In the interim, we provide user instructions that will enable you to ensure that your system will avoid this problematic situation. The instructions are also found in the attached Addendum A. These new user instructions should be implemented immediately and remain in effect until further notice. Your Agfa Service representative is available to assist you in implementing this solution.

Should you have questions or need assistance, please contact our Customer Support Center. The Agfa Customer Support Center can be toll-free at 877-777-2432.

This is an important and serious issue. Agfa requests acknowledgement of this letter in order to ensure that you have received and understand the gravity of this message. Please execute the acknowledgement below and return it in the stamped, self-addressed envelope enclosed.

Thank you for your understanding regarding this situation and your continued faith in Agfa products.

Sincerely,

M. Ted Ciona
Sr. Marketing Manager,
Digital Projection Radiography Systems
Agfa Corporation

CUSTOMER ACKNOWLEDGEMENT OF ADC ID PRODUCT UPATE

I have read and understand the issue presented and the instructions for correction in the attached Addendum's

Name of Institution: _____

Signature: _____Date: _____

Name (please print): _____

Title (please print): _____

Addendum A – Product Issue Circumstance and Recommended Procedure to Mitigate the Problem

Product Issue Circumstance:

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The user retrieves examination information from the RIS to the PRID and modifies the data manually. The data maybe changed manually by using the "New Patient" button, "History List", "Patient List", "Recall" button or entering data manually on the PRID or processing station. Consequently, the patient data from the RIS is overwritten, while the StudyUID remains the same, or in other words, the StudyUID is linked to different patient demographics on the RIS and on the PRID.

System Configuration: ADC, RIS and PACS (where the study instance UID is not transferred from the RIS to the PRID) or ADC and PACS without RIS:

The user retrieves examination information from the RIS to the PRID, or enters the data manually. The data (including StudyUID created by the PRID) will be related to the cassette / image, and sent via the processing station to the PACS system. When the user sends the study again with modified information to the PACS, this modification can be lost.

System Configuration: ADC workstation only

Conditions: The user corrects patient data via the info dialog

The user inadvertently misidentifies the patient or study (e.g. keeping the previous patient data or typing an error in an ID or name) and attempts to correct the information via the info dialog on the workstation. The user may unknowingly modify other patient images or studies.

Recommended Procedure to Mitigate the Problem:

The user should only modify patient data after transferring the information to the Picture Archival and Communication System.